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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,589	10/24/2003	Renzo Montanari	38068/GM/cb	7305

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EXAMINER

DRYDEN, MATTHEW DUTTON

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,589

Applicant(s)

MONTANARI, RENZO

Examiner

Matthew D. Dryden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment submitted on January 30, 2006.

Examiner acknowledges the cancellation of claims 1 and 2 and the addition of new claims 3-11 in response to the first office action.

Specification

Examiner acknowledges the change in the title of the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim recites the limitation of the external face comprising a cavity that is formed externally to the stopper and is of a spherical dome shape is integral with the stopper of the applicant's invention (see Figure 3), it is unclear what the applicant is referring to as the cavity formed externally of the stopper.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 4, 7, 8, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Micheli (4204606).

Regarding claim 3, Micheli discloses a tube and stopper combination comprising:
a stopper (element 12 in Figure 1) comprising a front external face (see around element 15 in Figure 1),

a piercing guiding point suitable for a hollow needle to pierce axially therein (see around element 16 in Figure 1), piercing guiding point is any point below central opening 16,

a peripheral region (towards the exterior of element 15 in Figure 1), and a central region (around element 17 in Figure 1) of the external face,

central region being provided with an opening for allowing needle access to said piercing guiding point (see element 16 in Figure 1),

an annular lip (element 17 in Figure 1),

the annular groove formed under said annular lip can be seen as the corners of element 14 in Figure 1, wherein a groove is just an open space,

the annular groove mentioned above surrounds the piercing guiding point mentioned above,

and the groove is shaped to retain any blood drop that is entrained out of the tube.

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Regarding claim 4, the cavity external the stopper (element 12 in Figure 1), can be seen as the space 14 in Figure 1.

Regarding claim 7, the external cavity comprises an edge (top corner of element 14 in Figure 1), the annular lip protrudes radially inward from said edge so as to surround said central region opening, and forms the annular groove that surrounds the piercing guiding point (see Figure 1).

Regarding claim 8, the opening of Micheli is shaped so as to allow at least free passage of the needle covered by an elastic sheath.

Regarding claim 9, the stopper of Micheli comprises a bottom, inner face (see bottom of element 12 in Figure 1) formed by a collar (around element 13 in Figure 1) and by a concentric cylindrical protrusion that is enclosed by said collar (see the raised protrusion at the base of element 12 in Figure 1), that allows the tube to be engageable with a mouth part thereof in said seat (between collar 13 and aforementioned protrusion), that is capable of double, inner and outer sealing engagement of the tube (see Figure 2).

Regarding claim 11, Micheli discloses a tube and stopper combination comprising:

a stopper (element 12 in Figure 1) comprising a front external face (see around element 15 in Figure 1),

a piercing guiding point suitable for a hollow needle to pierce axially therein (see around element 16 in Figure 1), piercing guiding point is any point below central opening 16,

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the stopper further comprises:

central region being provided with an opening for allowing needle access to said piercing guiding point (see element 16 in Figure 1),

a peripheral region (towards the exterior of element 15 in Figure 1), and a central region (around element 17 in Figure 1) of the external face and the cavity external the stopper (element 12 in Figure 1), can be seen as the space 14 in Figure 1,

the piercing guiding point is located in the cavity,

an annular lip (element 17 in Figure 1),

the annular groove formed under said annular lip can be seen as the corners of element 14 in Figure 1, wherein a groove is just an open space,

the annular groove mentioned above surrounds the piercing guiding point mentioned above,

and the groove is shaped to retain any blood drop that is entrained out of the tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 10 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Micheli in view of Rilliet (4434802). Micheli discloses the claimed invention except for the cavity having a spherical dome shape. Rilliet shows that is known to provide a

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cavity with a spherical dome shape (see around element 23 in Figure 3), to ensure the capture and maintenance of possible blood spills. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Micheli to include a cavity with a spherical dome shape, as taught by Rilliet, to ensure the capture and maintenance of possible blood spills.

Regarding claim 10, Micheli discloses the claimed invention except for the device comprising a needle arrangement comprising a needle-piercing end covered by an elastic sheath. Rilliet teaches it is known to provide a stopper assembly with a needle comprising an end that is covered with a rubber sleeve so that the stopper can be pierced and blood can be sampled from the patient (see Column 5, lines 4-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Micheli with a needle arrangement comprising a needle piercing end covered by an elastic sheath, as taught by Rilliet, so that the stopper can be pierced and blood can be sampled from the patient.

Micheli discloses a stopper comprising:

a peripheral region (towards the exterior of element 15 in Figure 1), and a central region (around element 17 in Figure 1) of the external face,

central region being provided with an opening, which is suitable to allow free passage of the needle piercing end, for allowing needle access to said piercing guiding point (see element 16 in Figure 1),

an annular lip (element 17 in Figure 1),

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the annular groove formed under said annular lip can be seen as the corners of element 14 in Figure 1, wherein a groove is just an open space,

the annular groove mentioned above surrounds the piercing guiding point mentioned above,

and the groove is shaped to retain any blood drop that is entrained out of the tube.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Micheli in view of Gunne et al (4163500). Micheli discloses the claimed invention except for the stopper having a hollow provided centrally in said cavity. Gunne et al teach it is known to provide a stopper with a hollow (element 16 in Figure 2) in the center of the cavity to allow the needle to pass relatively freely through the stopper while still maintaining a seal (see Column 3, lines 56-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Micheli to include a hollow located centrally in the cavity, as taught by Gunne et al, to allow the needle to pass relatively freely through the stopper while still maintaining a seal.

Response to Arguments

Applicant's arguments with respect to claims 3-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD



MARK MENDENBURG
PATENT EXAMINER
CENTER 3700